

Member FINRA/SIPC

Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Bluejay Diagnostics (NASDAQ: BJDJ) - Buy

June 28, 2022

De Novo Review Appears Viable for Symphony's IL-6 Test

Jason Kolbert
Managing Director & Senior Analyst
jkolbert@dawsonjames.com

Bluejay Diagnostics reported receiving regulatory feedback that Bluejay's Symphony IL-6 Test could be considered for the De Novo pathway. What this means is that regulators agree to consider the IL-6 test as new and novel and not comparable to other tests on the market today.

Bluejay's Symphony Appears Novel. Bluejay has filed its Pre-Submission application with the FDA for the Symphony IL-6 Test and plans to initiate an expanded clinical testing program. The results from this clinical program form the basis of the company's planned 510(k) marketing application, intended to be submitted in Q3:22. We also take note of the fact the Bluejay has appointed Edwin Rule as Vice President, Regulatory, Quality and Compliance.

Regulatory, Quality & Compliance - Edwin Rule: *Mr. Rule is a highly credentialed regulatory, quality and compliance professional with more than 15 years of industry experience. He has extensive training and expertise in medical device regulations in the U.S. and numerous international markets. In addition, he brings vast experience in FDA medical device submissions, Quality/Regulatory requirements for documentation, records and process qualification and Quality System Auditing. Mr. Rule also brings a track record in developing and implementing quality systems, building bridges to effectively work with the FDA and other regulatory agencies and leading high-performance teams.*

What is Symphony? Symphony is an automated diagnostic system consisting of a fluorescence immuno-analyzer that uses a single-use diagnostic test cartridge with reagents integrated into the cartridge. Symphony utilizes a 'sample-to-result' format, which means that once a specimen is taken from the patient, it is placed in the cartridge. Then the cartridge is placed inside the analyzer, where the test is run in minutes without further technician intervention or additional reagent.

A Paradigm Shift – A Rapid Point of Care Test for IL-6: Bluejay's IL-6 test for sepsis triage is intended to measure IL-6 levels in whole blood samples in near-patient settings. Interleukin-6 (IL-6) is an established biomarker of immune system activation. It is elevated in infection, inflammation, and cancer. IL-6 presents as an early "first responder" and needs to be measured quickly and reliably.

Valuation: We project our model out to 2030. We apply a conservative 30% success probability to our projected revenues in our Symphony product model in addition to our 30% risk rate applied in our Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models, which are then equal-weighted and averaged and rounded to the nearest whole number to derive our 12-month projected price target of \$8.0.

Risks to our thesis include: 1. Regulatory Approvals; 2. Clinical Science 3. Dependence on OEM suppliers; 4. Development of the target markets 5. Intellectual Capital 6. Dilution.



Risks to our thesis include: (1) Regulatory Approvals; (2) Clinical Science (3) Dependence on OEM suppliers; (4) Development of the target markets (5) Intellectual Capital (6) Dilution Risks. In addition, the company details the following additional risks:

- The company is likely to incur losses for the foreseeable future until it is able to generate sufficient revenue from product sales.
- Losses from operations could raise doubts regarding the company's ability to continue as a going concern. The ability to continue as a going concern likely requires additional funding to finance the company's operations.
- The company's product candidates are dependent on its license agreement with Toray. The license agreement imposes significant obligations on the company, including the potential obligation to pay the minimum royalties upon regulatory approval. If the company's license agreement with Toray is terminated for any reason, the company may not be able to generate revenues, and its business could cease.
- The regulatory approval pathway the company must navigate may be expensive, time-consuming and uncertain, and may prevent the company from obtaining approval for the marketing of its product candidates.
- There can be no assurance that the company will successfully complete any clinical evaluation studies necessary to receive regulatory approvals.
- The company's success is highly dependent on its IL-6 product candidates, which are yet to be approved and, even if approved, may not be accepted by the marketplace.
- The company is dependent on third parties to manufacture its product candidates.
- If Toray is unable to successfully protect or enforce its intellectual property and proprietary rights or elects not to do so, the company's competitive position will be harmed.
- If others claim that the company or Toray are infringing on their intellectual property rights, the company may be subject to costly and time-consuming litigation.
- The company may face competition from companies that have greater resources creating a tough to compete environment.

Exhibit 1. Income Statement

BJDX, Inc. Income Statement (\$000)																		
YE Dec. 31	2021A	1Q22A	2Q22E	3Q22E	4Q22E	2022E	1Q23E	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue (\$000)																		
Symphony Revenues - IL6 (risk adjusted probability)	-	-	-	-	-	-	2,426	2,527	2,527	2,628	10,109	30,326	73,289	126,360	196,560	270,270	324,324	378,378
Symphony Revenues - Non- IL6													2,000	5,000	15,000	25,000	35,000	40,000
Total Revenues	-	-	-	-	-	-	2,426	2,527	2,527	2,628	10,109	30,326	75,289	131,360	211,560	295,270	359,324	418,378
Expenses																		
COGS	-	-	-	-	-	-	1,213	1,264	1,264	1,314	5,054	15,163	30,116	45,976	63,468	88,581	107,797	125,513
% COGS							50%	50%	50%	50%	50%	50%	40%	35%	30%	30%	30%	30%
Gross Profit	-	-	-	-	-	-	1,213	1,264	1,264	1,314	5,054	15,163	45,173	85,384	148,092	206,689	251,527	292,865
Research & Development	1,148	695	201	201	(293)	804	240	250	250	260	1,000	2,000	2,040	2,081	2,122	2,165	2,208	2,252
General & Administrative	1,792	1,320	1,250	1,250	1,180	5,000	1,224	1,275	1,275	1,326	5,100	5,202	5,306	5,412	5,520	5,631	5,743	5,858
Marketing & Business Development	290	54	74	74	94	296	72	75	75	78	301	2,000	4,000	6,000	6,120	6,242	6,367	6,495
Total expenses	3,230	2,068	1,525	1,525	981	6,098	1,536	1,600	1,600	1,664	6,401	9,202	11,346	13,493	13,763	14,038	14,319	14,605
Operating Profit	(3,230)	(2,068)	(1,525)	(1,525)	(981)	(6,098)	(323)	(337)	(337)	(350)	(1,347)	5,961	33,827	71,891	134,329	192,651	237,208	278,259
Oper Margin																		
Interest Income (expense)	(258)	55				55					-	-	-	-	-	-	-	-
Other Income	-					-					-	-	-	-	-	-	-	-
Pre-tax income	(3,488)	(2,013)	(1,525)	(1,525)	(981)	(6,043)	(323)	(337)	(337)	(350)	(1,347)	5,961	33,827	71,891	134,329	192,651	237,208	278,259
Pretax Margin																		
Income Tax (Benefit)														7,189	26,866	57,795	94,883	111,304
Tax Rate		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	20%	30%	40%	40%
GAAP Net Income	(3,488)	(2,013)	(1,525)	(1,525)	(981)	(6,043)	(323)	(337)	(337)	(350)	(1,347)	5,961	33,827	64,702	107,463	134,856	142,325	166,956
GAAP-EPS	(0.41)	(0.10)	(0.08)	(0.08)	(0.05)	(0.30)	(0.02)	(0.01)	(0.01)	(0.01)	(0.05)	0.20	1.10	2.09	3.45	4.30	4.51	5.25
Non GAAP EPS (dil)	(0.41)	(0.10)	(0.08)	(0.08)	(0.05)	(0.30)	(0.02)	(0.01)	(0.01)	(0.01)	(0.05)	0.20	1.10	2.09	3.45	4.30	4.51	5.25
Wgtd Avg Shrs (Bas) - '000s	8,522	20,142	20,182	20,223	20,263	20,203	20,304	30,344	30,405	30,466	27,880	30,618	30,864	31,112	31,361	31,613	31,867	32,122
Wgtd Avg Shrs (Dil) - '000s	8,522	20,142	20,182	20,223	20,263	20,203	20,182	30,223	30,283	30,344	27,758	30,465	30,679	30,894	31,111	31,330	31,549	31,771

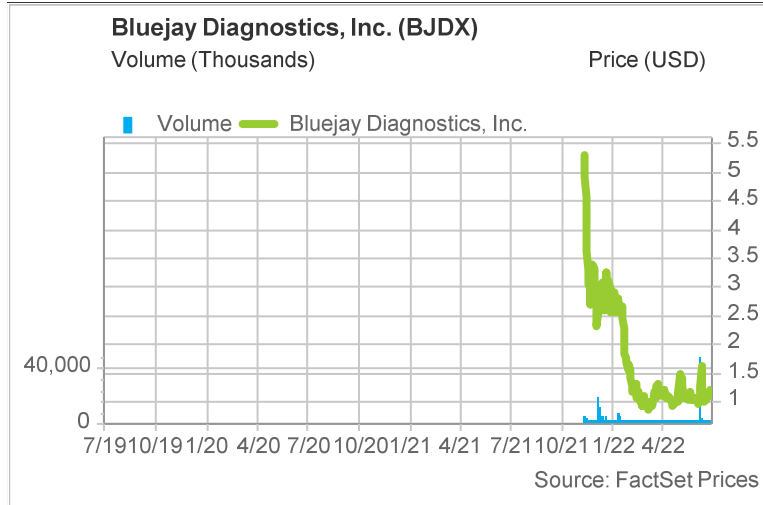
Source: Company reports and Dawson James

Companies mentioned in this report:

Toray (Japan)

Important Disclosures:

Price Chart:



Price target and ratings changes over the past three years:

- Initiated – Buy – January 12, 2022 – Price Target \$10.0
- Update – Buy – January 14, 2022 – Price Target \$10.0
- Update – Buy – January 31, 2022 – Price Target \$10.0
- Update – Buy – March 10, 2022 – Price Target \$10.0
- Update – Buy – April 21, 2022 – Price Target Change \$10.0 to \$8.0
- Update – Buy – June 28, 2022 – Price Target \$8.0

Dawson James Securities, Inc. (the "Firm") is a member of the Financial Industry Regulatory Authority ("FINRA") and the Securities Investor Protection Corporation ("SIPC").

The Firm does not make a market in the securities of the subject company(s). The Firm has engaged in investment banking relationships with the subject company in the prior twelve months, as a manager or co-manager of a public offering and has received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has not received any other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director, or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of June 16, 2022, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts, or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

Information about valuation methods and risks can be found in the "Valuation" and "Risk Analysis" sections of this report.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

Ratings Definitions:

- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months.
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months.
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies, followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 16-Jun-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	72%	4	13%
Market Perform (Neutral)	12	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	43	100%	4	9%

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.